IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

OFFORD, Robin E. et al.

Appl. No. To Be Assigned

Filed: Herewith

For: Polypeptide and Protein

Derivatives and Process for Their

Preparation

Art Unit: To be Determined

Examiner: To be Determined

Atty. Docket: 03504-115-CON

Information Disclosure Statement Pursuant to 37 C.F.R. § 1.97(b)(1)

Honorable Commissioner of Patents PO Box 1450 Alexandria VA 22313-1450

Dear Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents may be found in the file histories of Applicants' parent applications:

- U.S. Patent Application Serial No. 08/241,687, filed May 12, 1994;
- U.S. Patent Application Serial No. 08/089,051, filed August 6, 1993;
- U.S. Patent Application Serial No. 07/866,262, filed April 10, 1992;
- U.S. Patent Application Serial No. 07/742,159, filed August 1, 1991;
- U.S. Patent Application Serial No. 07/506,545, filed April 5, 1990;
- U.S. Patent Application Serial No. 07/380,738, filed July 17, 1989;
- U.S. Patent Application Serial No. 07/220,196, filed July 18, 1988; and
- U.S. Patent Application Serial No. 07/043,530, filed on April 28, 1987.

The Examiner is requested to contact an undersigned immediately in the event that any cited document may be unavailable, in order that a replacement copy can be provided.

This Information Disclosure Statements is being submitted prior to an Initial Office Action. No fee is accordingly believed due for consideration of this Information Disclosure Statement. However, if the Commissioner determines that an additional fee is required in for consideration of this Information Disclosure Statement, the U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account No. 50-0548 referencing docket number 3504.115-CON.

The submitted documents are:

AA1	U.S. Patent No. 4,691,006	Stevens
AB1	U.S. Patent No. 4,699,784	Shih et al.
AC1	U.S. Patent No. 3,903,069	Gregory et al.
AD1	U.S. Patent No. 4,707,352	Stavrianpoulos
AE1	U.S. Patent No. 4,352,751	Wieder et al.
AF1	U.S. Patent No. 3,856,771	Jackson
AA2	U.S. Patent No. 3,864,325	Smyth
AB2	U.S. Patent No. 4,029,642	Obermeier
AC2	U.S. Patent No. 4,183,849	Hansen et al.
AD2	U.S. Patent No. 5,045,451	Uhr et al.
AE2	U.S. Patent No. 5,106,951	Morgan et al.
AF2	U.S. Patent No. 4,722,899	Hamaoka et al.

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AL1	EP 0 088 695
AM1	EP 0 243 929
AN1	JP 2528464
AL2	JP 3525/72
AM2	WO 90/02136
AR1	Bayer, E.A. at al., "The Avidin-Biotin Complex in Affinity Cytochemistry," Methods in Enzymology 62: 308 (1979)
AS1	Brady et al., Selective Decrease in T Relaxation Times," abstract, Magnetic Resonance in Medicine 1: 286 (1984)
AT1	Canova-Davis, E. et al., "Semisynthesis of insulin: specific activation of the arginine carboxyl group of the B chain of desoctapeptide-(B2330)-insulin (bovine)," Biochemistry 20: 7053 (1981)
AR2	Chua, M.M. et al., "Attachment of immunoglobulin to Liposomal Membrane Via Protein Carbohydrate," Biochim. Biophys. Acta 800: 291 (1984)
AS2	Dixon et al., "Specific Modification of NH2 – Terminal Residues by Transamination,", Methods in Enzymology 25: 409 (1979)
AT2	Fields et al., "A Spectrophotometric Method for the Microdetermination of Periodate," Biochem J. 108: 883 (1968)
AR3	Friedman et al., "Reductive Alkylation of Proteins With Aromatic Aldehydes and Sodium Cyanoborohydride," Int. J. Peptide Protein Res. 6: 183 (1974)
AS3	Gray, "The Direct Coupling of Oligosaccharides to Proteins and Derivatized Gels," Gels, Arch. Biochem. Biophys. 163: 426 (1974)
AT3	Hansske et al., "Modification of the 3 Terminus by Periodate Oxidation," Methods in Enzymology LIX: 172 (1979)

- 3 -

Information Disclosure Statement
Pursuant to 37 C.F.R. § 1.97(b)(1)

AR4 Heitzmann et al., Use of the Avidin-Biotin Complex for Specific Staining of Biological Membranes..., Proc. Natl. Acad. Sci. USA 71: 3537 (1974) Hermentin et al., "Investigations with monoclonal antibody drug AS4 (anthracycline) conjugates," Behring Inst. Mitt No. 82 P. 197-215 (1988) AT4 Hnatowich et al., "Radioactive Labeling of Antibody: A Simple And Efficient Method," Science 220: 613 (1983) Hofmann et al., "Avidin Binding of Carboxyl-Substituted Biotin and AR5 Analogues," Biochemistry 21: 978 (1982) AS5 Itaya et al., "Cell Surface Labeling of Erythrocyte Glycoproteins...", Biochem. Biophys. Res. Commun. 64: 1028 (1975) Jentoft et al., "Protein Labeling by Reductive Alkylation," Methods in AT5 Enzymology 91: 570 (1983) AR6 Ji, "Bifunctional Reagents," Methods in Enzymology 91: 580 (1983) Jones et al., "The Proteinase-Catalysed Synthesis of Peptide Hydrazides," AS6 Biochem. J 203: 125 (1982) King et al., "Preparation of Protein Conjugates Via Intermolecular AT6 Hydrazone Linkage," Biochemistry 25: 5774 (1986) Kraehenbuhl et al., "Preparation and Characterization of an Immuno-AR7 Electron Microscope Tracer," J. Exp. Med. 139: 208 (1974) AS7 Kreicarek et al., "Covalent Attachment of Chelating Groups to Macromolecules," Biochem. Biophys. Res. Commun. 77: 581 (1977) Leibiger et al., "Structural Characterization of the Oligosaccharides of a AT7 Human Monoclonal Anti-Lipopolysaccharide Immunoglobulin M," Glycobiology p. 497-507 (1998) Mach et al., "Tumor Localization in Patients by Radiolabeled Monoclonal AR8 Antibodies," Cancer Res. 43: 5593 (1983) Mikolajczyk et al. "High Yield, Site-Specific Coupling of N-Terminally AS8 Modified s-Lactamase to a Proteolytically Derived Single-Suifhydryl,"

Bioconjugate Chem. Vol. 5 No. 6

AT8	Murayama et al., "Modification of Immunoglobulin G Using Specific Reactivity of Sugar Moiety," Immunochem. 15: 523 (1978)
AR9	Quash et al., "The Preparation of Latex Particles with Covalently Bound Polyamines," J. Immunol. Methods 22: 165 (1978)
AS9	Rodwell et al., "Site-Specific Covalent Modification of Monoclonal Antibodies," Proc. Natl. Acad. Sci. USA 83: 2632 (1986)
АТ9	Seaver, Genetic Engineering News p. 10 and 21 (1994)
AR10	Wagner et al., "Gallium-68 Labeling of Albumin and Albumin Microspheres," J Nucl Med p. 428-433 (1979)
AS10	Waldmann, "Monoclonal antibodies in diagnosis and therapy," Science 252:1657-1661 (1991)
AT10	Werlen, et al., "Site-Specific Immunoconjugates," Tumor Targeting p. 251-258 (1995)

- 5 -

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application.

Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicant respectfully requests that the documents listed on the accompanying Form PTO 1449 be considered and made of record in the present application.

Applicant further requests that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

While the listed references are considered relevant to the prosecution of the present application, it is submitted that the references, either alone or in combination, do not detract from the patentability of the claimed invention.

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Date: 9/39/2

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effrey I. Auerbach

Registration No. 32,680 Attorney for Applicant

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	AA1	4,691,006	09/01/1987		Stevens	530	324	11/02/1984		
	AB1	4,699,784	10/13/1987		Shih et al.	424	181.1	02/25/1986		
	AC1	3,903,069	09/02/1975		Gregory et al.	260	112.7	11/30/1973		
	AD1	4,707,352	11/17/1987		Stavrianpoulos	424	1.17	01/30/1984		
	AE1	4,352,751	10/05/1982		Wieder et al.	530	303	09/10/1979		
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	AL1	EP 0 088 695	9/1983		Europe	G01N	33/53	No		
	AM1	EP 0 243 929	9/1995		Europe	C07K	14/00	No		
	AN1	JP 2528464	6/1996		Japan	C07K	14/00	No		
	AR1	Bayer, E.A. at a	l., "The Avidin	n-Bio	Title, Date, Pertinent Potin Complex in Affinity Cytoc	hemistry,"	Methods in			
	AS1	Brady et al., Sel			T Relaxation Times," abstrac					
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	AR2	Carbohydrate."	Biochim, Bio	phys	immunoglobulin to Liposomo s. Acta 800: 291 (1984)					
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	AR4	Proc. Natl. Aca	d. Sci. USA 7	1:35						
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Title: Polypeptide and Protein Derivatives		Applicant: OFFORD, Robin E. et al.							
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	AA2	3,864,325	02/04/1975	Sm	vth		260	112.7	11/13/1972
	AB2	4,029,642	06/14/1977		ermeier		530	303	12/19/1975
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	AD2	5,045,451	09/03/1991		et al.		435	7.23	10/26/1988
	AE2	5,106,951	04/21/1992		rgan et al.		530	391.9	03/31/1989
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	AM2	WO 90/02136	3/1990	PC			C07K	3/08	No
	AS5	Commun. 64: 10 Jentoft et al., "Pr	28 (1975) otein Labelin	ng by Red	Erythrocyte Glycoprot ductive Alkylation," M	ethods	in Enzy		
	AR6				n Enzymology 91: 580				
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	AS7	Res. Commun. 7	7: 581 (1977))	t of Chelating Groups				
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	AR8	43: 5593 (1983)			atients by Radiolabele				
	AS8	Proteolytically L	erived Single	e-Suifhya	pecific Coupling of N-7 Iryl," Bioconjugate Ch	em. Vo	l. 5 No.	. 6	
	AT8	Immunochem. 13	5: 523 (1978))	nunoglobulin G Using				
	AR9	Methods 22: 165	(1978)		x Particles with Coval				
	AS9	Sci. USA 83: 26:	32 (1986)		Modification of Mono	clonal .	Antiboo	dies," Proc	Natl. Acad.
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PTO 1449 INFORMATION DISCLOSURE STATEMENT Title: Polypeptide and Protein Derivatives and Process for Their Preparation U.S. PATENT DOCUMENTS Page 3 of 3 Atty Dkt: 03504-115-CON Serial No. To Serial No. To Decivative	o be Assigned
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